

General Information

Physician office laboratories that accept 100 or more specimens during a calendar year on referral from other physicians are certified by Wisconsin Medicaid as independent laboratories, and they are covered by the policies described in this handbook.

The Independent Laboratory Services Handbook includes information for Medicaid-certified independent laboratories on provider eligibility, recipient eligibility, covered services, reimbursement methods, and billing instructions. Use this handbook in conjunction with the All-Provider Handbook, which includes general policy guidelines, regulations, and billing information applicable to all types of certified providers.

The Independent Laboratory Services Handbook explains policies governing all Medicaid-certified independent laboratories that examine specimens from Medicaid recipients for health assessment or for the diagnosis, prevention, or treatment of any disease or health impairment.

Refer to the Laboratory and Radiology Services section of the Physician Services Handbook for Wisconsin Medicaid's policies that govern laboratory services provided by physician office laboratories.

Refer to the Medicaid Inpatient and Outpatient Hospital State Plans and to the Physician Services Handbook for Medicaid policies that govern laboratory services provided by hospital laboratories.

Provider Information

Independent Laboratory Certification Criteria

To become a Medicaid-certified independent laboratory service provider, Wisconsin Medicaid requires the laboratory to meet the following requirements:

- The laboratory must be independent of an attending or consulting physician's office and hospital. Wisconsin Medicaid may consider a laboratory as independent if the laboratory under a physician's direction is located outside a hospital.

- The laboratory must be Medicare certified.
- The laboratory must have a current, verified, unrevoked, and not suspended Clinical Laboratory Improvement Amendment (CLIA) certificate or CLIA waiver.
- The laboratory's services and office facilities must be available to other physicians for performing diagnostic tests.

A laboratory is not independent if it is either of the following:

- Located in a hospital and operated under a hospital's supervision.
- Operated under a hospital's organized medical staff and serves the hospital's patients.

Physician office laboratories that accept 100 or more specimens during a calendar year on referral from other physicians are certified by Wisconsin Medicaid as independent laboratories, and they are covered by the policies described in this handbook.

A laboratory that is not an independent laboratory may perform laboratory services for Wisconsin Medicaid under another Medicaid certification when the following two conditions are met:

1. The performing provider, such as the supervising physician, is a Medicaid-certified provider.
2. The laboratory provider has a current, verified, unrevoked, and not suspended CLIA certificate or CLIA waiver.

Clinical Certification for Laboratory Services

Congress implemented CLIA to improve the quality and safety of laboratory services. CLIA requires all laboratories and providers performing tests for health assessment or for

the diagnosis, prevention, or treatment of disease or health impairment to comply with specific federal quality standards.

CLIA Enrollment

The federal Centers for Medicare and Medicaid Services (CMS), formerly HCFA, sends CLIA enrollment information to Wisconsin Medicaid. The enrollment information includes CLIA identification numbers for all current laboratory sites. Wisconsin Medicaid verifies that laboratories are CLIA-certified before issuing a Medicaid provider billing number.

CLIA Regulations

Wisconsin Medicaid complies with the following federal regulations as initially published and subsequently updated:

- Public Health Service Clinical Laboratory Improvement Amendments of 1988.
- 42 CFR Part 493, Laboratory Requirements.

Scope of CLIA

CLIA governs all laboratory operations including the following:

- Accreditation.
- Certification.
- Fees.
- Patient test management.
- Personnel qualifications.
- Proficiency testing.
- Quality assurance.
- Quality control.
- Records and information systems.
- Sanctions.
- Test methods, equipment, instrumentation, reagents, materials, and supplies.
- Tests performed.

CLIA regulations apply to all Wisconsin Medicaid providers who perform

laboratory services, including, but not limited to, the following:

- Clinics.
- HealthCheck providers.
- Independent clinical laboratories.
- Osteopaths.
- Physician assistants.
- Physicians.
- Rural health clinics.


CLIA Certification Types

The CMS regulations require providers to have a CLIA certificate that indicates the laboratory is qualified to perform a category of tests.

Clinics or groups with a single Medicaid billing number, but multiple CLIA numbers for different laboratories, may wish to contact Wisconsin Medicaid Provider Services to discuss various certification options.

The CMS issues five types of certificates for laboratories:

1. *Waiver certificate.* This certificate allows a laboratory to perform waived tests only. Refer to Appendix 1 of this handbook for a list of waived procedures, including those procedures that must be billed with a “QW” modifier.
2. *Provider-performed microscopy procedures certificate.* This certificate allows a physician, mid-level practitioner (i.e., nurse midwife, nurse practitioner, or physician assistant licensed by the State of Wisconsin), or dentist to perform microscopy and waived procedures only. Refer to Appendix 2 of this handbook for a list of Medicaid-allowable CLIA provider-performed microscopy procedures.
3. *Registration certificate.* This certificate allows a laboratory to conduct moderate or high complexity tests until the laboratory is determined to be in compliance through a CMS survey performed by the Wisconsin State Agency for CLIA.



Clinics or groups with a single Medicaid billing number, but multiple CLIA numbers for different laboratories, may wish to contact Wisconsin Medicaid Provider Services to discuss various certification options.



Providers must immediately notify the Clinical Laboratory Unit of changes in certificate types

4. *Compliance certificate.* This certificate is issued to a laboratory (for moderate and/or high complexity tests) after a CMS inspection performed by the State Agency finds the laboratory in compliance with all applicable complexity-level requirements.
5. *Accreditation certificate.* This certificate is issued on the basis of the laboratory's accreditation by a CMS-approved accreditation organization. The six major approved accreditation organizations are:
 - American Association of Blood Banks (AABB).
 - American Osteopathic Association (AOA).
 - American Society for Histocompatibility and Immunogenetics (ASHI).
 - COLA.
 - College of American Pathologists (CAP).
 - Joint Commission on Accreditation of Healthcare Organizations (JCAHO).

Use the HCFA-116 CLIA application to obtain program certificates. You may obtain HCFA-116 forms from the following address:

Clinical Laboratory Unit
Bureau of Quality Assurance
Division of Supportive Living
PO Box 2969
Madison WI 53701-2969

Providers must notify the Clinical Laboratory Unit in writing within 30 days of any change(s) in ownership, name, location, or director.

Providers must immediately notify the Clinical Laboratory Unit of changes in certificate types. When a specialty or subspecialty is added or deleted, providers must notify the Clinical Laboratory Unit within six months. Providers may contact the Clinical Laboratory Unit at (608) 266-5753.

Provider Responsibilities

Refer to the Provider Rights and Responsibilities section of the All-Provider Handbook for information about the

responsibilities of Medicaid-certified providers, including all of the following:

- Fair treatment of recipients.
- Maintenance of records.
- Recipient requests for noncovered services.
- Services rendered to a recipient during periods of retroactive eligibility.
- Grounds for provider sanctions.
- Additional state and federal requirements.

Recipient Information

Verifying Recipient Eligibility

Wisconsin Medicaid providers should verify recipient eligibility and identify any limitations to the recipient's coverage *before* providing services. Refer to the All-Provider Handbook for detailed information on accessing the Eligibility Verification System and eligibility for Wisconsin Medicaid. For telephone numbers regarding recipient eligibility, refer to the page of Important Telephone Numbers at the beginning of this handbook.

Copayment

Wisconsin Medicaid does not require a recipient copayment for independent laboratory services.

Coordination of Benefits

Health Insurance Coverage

In most cases, Wisconsin Medicaid is the payer of last resort for any Medicaid-covered service. If a recipient is covered under commercial health insurance, Wisconsin Medicaid reimburses that portion of Medicaid's allowable cost remaining after commercial health insurance sources have been exhausted.

In some cases, Wisconsin Medicaid is the primary payer and must be billed *first*. Payers secondary to Wisconsin Medicaid include governmental programs such as:

- Birth to 3.
- The Crime Victim Compensation Fund.
- General Assistance.
- Title V of the Social Security Act, Maternal and Child Health Services, relating to the Program for Children with Special Health Care Needs.
- The Wisconsin Adult Cystic Fibrosis Program.
- The Wisconsin Chronic Renal Disease Program.
- The Wisconsin Hemophilia Home Care Program.

Refer to the Coordination of Benefits section of the All-Provider Handbook for more information on services requiring health insurance billing, exceptions, the Other Coverage Discrepancy Report, and payers secondary to Wisconsin Medicaid.

Medicare Coverage

Recipients covered under both Medicare and Wisconsin Medicaid are referred to as dual entitlees. Claims for Medicare-covered services provided to dual entitlees must be billed to Medicare prior to Wisconsin Medicaid.

Independent laboratories not certified by Medicare may be retroactively certified by Medicare for the date a service was provided. Contact the appropriate Medicare fiscal intermediary for certification information.

Providers are required to accept assignment on Medicare claims for dual entitlees. The dual

entitlee is not liable for Medicare's coinsurance or deductible.


Usually, *Medicare-allowed* claims (called crossover claims) are automatically forwarded by Medicare to Wisconsin Medicaid for processing. If Wisconsin Medicaid has the provider's Medicare provider number, it will reimburse for the coinsurance and deductible within certain limits. These limits are described in the Coordination of Benefits section of the All-Provider Handbook. Wisconsin Medicaid reimburses for the coinsurance and deductible on crossover claims even if the service is not a Medicaid-covered service.

If the service provided to a dual entitlee is covered by Medicare (in at least some situations), but *Medicare denied* the service on a correctly completed claim, submit a new claim for the denied service to Wisconsin Medicaid and indicate the appropriate Medicare disclaimer code in Element 11 of the HCFA 1500 claim form. Refer to Appendix 6 (Element 11) of this handbook for a list of the Medicare disclaimer codes.

Qualified Medicare Beneficiary Only

Qualified Medicare Beneficiary-Only (QMB-Only) recipients are eligible *only* for Wisconsin Medicaid payment of the coinsurance and deductible for Medicare-allowed services.

Wisconsin Medicaid does not reimburse claims for QMB-Only recipients that Medicare does not allow. Independent laboratories are required to accept assignment on Medicare claims for QMB-Only recipients.



Claims for Medicare-covered services provided to dual entitlees must be billed to Medicare prior to Wisconsin Medicaid.